



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/155,514	11/17/98	KAINOH	M 1102-98

HM22/1213

SCHNADER HARRISON SEGAL & LEWIS
1600 MARKET STREET
36TH FLOOR
PHILADELPHIA PA 19103

EXAMINER
SCHWABRUN, R

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED:

12/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/155,514

Applicant(s)

Kainoh et al.

Examiner
Ron Schwadron, Ph.D.

Group Art Unit
1644



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) 10-23, 26-44 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9, 24, 25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election of Group I, claims 1-9,24,25 and the species molecule (1), claim 3 in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 10-23,26-44 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 15.

3. Claims 1-9 and 24,25 are under consideration.

4. The abstract of the disclosure is objected to because the abstract is two paragraphs and it needs to be one paragraph. Correction is required. See MPEP § 608.01(b).

5. Applicant needs to list the appropriate Seq. ID. Number wherever a sequence is disclosed in the specification (eg. page 10, line 2, page 63, page 64, etc.) See 37 CFR 1,821(d).

6. The amendment filed 9/25/2000 (and 1/10/2000) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

According to the amendment filed 1/10/2000, the designation "Try" has been changed to "Tyr" (tyrosine) in the submitted sequence listing. However, in view of the fact that the first three letters of tryptophan are "Try" it is not immediately apparent that the original "Try" was meant to designate tyrosine versus tryptophan. This issue can be addressed via a declaration from the Inventor(s).

Applicant is required to cancel the new matter in the reply to this Office action.

7. Regarding the sequences disclosed in Figure 3, said sequences need to be identified in the description of the figure in the Brief description of the drawings section and identified with a SEQ. ID. number.

8. Claims 24 and 25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 are indefinite in the recitation of "is identified as" because it is unclear what this means or encompasses. A preferred substitution is "is".

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1,24,25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallatin et al.

Gallatin et al. teach an α integrin chain extracellular domain/Ig constant domain fusion protein (see claim 19). The specification, page 11 discloses that "chimeric protein consisting of the α chain of an integrin and the heavy or light chain of an immunoglobulin" actually means "the extracellular region of the α chain of an integrin is bound to the constant region of the heavy chain or light chain contained an immunoglobulin". A similar definition is given for "chimeric protein consisting of the β chain of an integrin and the heavy or light chain of an immunoglobulin". The art recognizes that Ig constant domains are found in light or heavy chain of an Ig molecule. Regarding claims 24 and 25, the recitation of an intended use carries no weight in the instant product claims. However, Gallatin et al. does teach pharmaceutical compositions of soluble α integrin (page 12).

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-9,24,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent 5,821,333) in view of Hori et al. (US Patent 5,916,771) and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification).

Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. do not specifically teach that the adhesion molecules are derived from an α and β chain of an integrin. Hori et al. teach that β_1 integrin molecules were known in the art as heterodimeric molecules (see column 5). The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. The prior disclosed in the specification, page 3 indicates that β_1 integrin molecule was known in the art as heterodimeric molecule containing a β_1 and an $\alpha 4$ chain. Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Hori et al. teach recombinantly produced dimeric integrin molecules (see column 5). Carter et al. also teach recombinantly produced dimeric adhesion molecules (see columns 19 and 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule while Hori et al. teach that β_1 integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. One of ordinary skill in the art would have been motivated to do the aforementioned because Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Carter et al. teach use of Ig fusion proteins as drugs (see column 4). The various integrin molecules recited in the claims were all known in the art. Human Ig heavy chain sequences were known in the art (see Carter et al.,

columns 18 and 19).

15. No claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644